



## Mifepristone/misoprostol (medical abortion)

### Description

Medical abortion is a nonsurgical procedure in which drugs are used to induce abortion. The most effective and safest medical abortion regimen requires the use of two medications, mifepristone and misoprostol. The recommended regimen is 200mg of mifepristone given orally, followed 24 to 48 hours later by 800µg of misoprostol given vaginally up to 63 days since the last menstrual period.<sup>1</sup> Misoprostol can be given orally at a dose of 400µg, but due to the higher failure rate, it is recommended that oral misoprostol use at this dosage be limited to pregnancy under 50 days. Misoprostol can also be administered buccally or sublingually.<sup>2, 3</sup>

Mifepristone blocks the action of progesterin to enhance the contractility of the uterus and prompt the detachment of the implanted embryo. It also acts to soften and dilate the cervix. Misoprostol stimulates strong contractions of the uterus, expelling the products of conception. This process is very similar to that of a spontaneous abortion or miscarriage.<sup>4</sup> Repeated administration of misoprostol alone may lead to an abortion, but results in lower effectiveness rates and higher rates of side effects. However, misoprostol-only abortions may be an appropriate option in settings where mifepristone is not available.<sup>5</sup>

Quality abortion care should include counseling; confirmation of pregnancy; estimation of length of gestation; and screening for ectopic pregnancy by the patient's history, bimanual exam, or with ultrasound—although ultrasound is not required. Some settings offer a second visit to confirm the pregnancy is terminated. Contraceptive-options counseling should be provided at the time of the abortion or afterwards. The provision of safe abortion is an important component of reproductive health services. Medical abortion options have made abortion more available to women in a variety of health care settings.

### Efficacy

Based on extensive research, mifepristone and misoprostol as a combined regimen have a success rate of complete abortion at 96 percent and a rate of continued pregnancies at less than 1 percent.<sup>1</sup> Cramping and vaginal bleeding are associated and expected effects of medical abortions. Under medical supervision, the use of mifepristone and misoprostol is very safe. Medical abortion has not been associated with long-term health impacts and is statistically less risky than continuation of pregnancy.<sup>6</sup> Medical abortion may be preferable to surgical abortion for some women, largely due to the avoidance of risks associated with such procedures (e.g., complications of anesthesia), and also the fact that medical abortion is a less invasive and more private procedure.

### **Current program/sector use**

There are a number of political, logistical, cultural, religious, financial, and other barriers that limit universal access to medical abortion. Abortion is legally restricted in many countries. Where abortion is legal, challenges may arise in terms of health-system restrictions on where the services can be provided, procurement of the drugs (mifepristone products can be expensive, but lower cost products are becoming available), and provider training in order to properly inform and counsel patients about their options, the procedure, risks, and benefits. However, mifepristone and misoprostol are currently registered and being made available to women in numerous countries. The level of use in countries such as the United States suggests that women appreciate having an alternative to surgical abortion. Over 1 million women have used Mifeprex since it was registered in the United States in 2000.<sup>7</sup>

### **Manufacturer/supplier**

Mifepristone is branded as Mifegyne<sup>®</sup> by Exelgyn Laboratories and as Mifeprex<sup>®</sup> by Danco Laboratories. Misoprostol is most widely available as Cytotec<sup>®</sup>, which is manufactured and distributed by Pfizer; it is only registered by Pfizer for one indication—prevention and treatment of gastric ulcers secondary to chronic use of NSAIDs. Misoprostol products are registered for gynecological indications in countries such as Brazil, France, Russia, and Egypt, and registered specifically for use with mifepristone for pregnancy termination in France (registered by HRA Pharma as Gymiso<sup>®</sup>) and Russia (registered by Pentcroft Pharma as Misoprostol). The Concept Foundation has recently developed a new combination-pack mifepristone-misoprostol product (Medabon<sup>®</sup>) to be marketed in developing countries for medical abortion; it is currently registered for this indication in India and Nepal. For more information, visit [www.medabon.info](http://www.medabon.info). In addition, generic and nongeneric misoprostol products are available through additional suppliers (other than Pfizer) in India, China, Egypt, Vietnam, Taiwan, Korea, Colombia, Brazil, and the United Kingdom.

### **Registration status**

Mifepristone has been approved for use in 40 countries worldwide.<sup>8</sup> Misoprostol has been approved for use in 85 countries for treatment and prevention of gastric ulcers and less frequently for treatment of gynecologic conditions.<sup>9</sup> Mifepristone and misoprostol are listed on the WHO essential medicines list for use as abortifacients where legal and acceptable.<sup>10</sup>

### **Public-sector price agreements**

The Concept Foundation has negotiated a preferential price for the public-sector in developing countries for Medabon<sup>®</sup>.

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<sup>1</sup> World Health Organization (WHO). *Frequently Asked Clinical Questions About Medical Abortion: Conclusions of an International Consensus Conference on Medical Abortion in Early First Trimester, Bellagio, Italy*. Geneva: WHO; 2006.

<sup>2</sup> Winikoff B, Dzuba IG, Creinin MD, et al. Two distinct oral routes of misoprostol in mifepristone medical abortion: a randomized controlled trial. *Obstetrics and Gynecology*. 2008;112(6):1303–1310.

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<sup>3</sup> Tang OS, Chan C, Ng E, Lee S, Ho P. A prospective, randomized, placebo-controlled trial on the use of mifepristone with sublingual or vaginal misoprostol for medical abortions of less than 9 weeks gestation. *Human Reproduction*. 2003;18(11):2315–2318.

<sup>4</sup> International Consortium for Medical Abortions (ICMA). *The ICMA Information Package on Medical Abortion: Information for Health Care Providers*. London: ICMA; 2008.

<sup>5</sup> Misoprostol Alone page. Medical Abortion website. Available at: [www.medicationabortion.com/misoprostol/index.html](http://www.medicationabortion.com/misoprostol/index.html). Accessed September 15, 2008.

<sup>6</sup> Grimes DA. Estimation of pregnancy-related mortality risk by pregnancy outcome, United States, 1991 to 1999. *American Journal of Obstetrics and Gynecology*. 2006;194(1):92–94.

<sup>7</sup> Mifeprex in the United States page. Mifeprex website. Available at: [http://www.earlyoptionpill.com/section/health\\_professionals](http://www.earlyoptionpill.com/section/health_professionals). Accessed February 11, 2009.

<sup>8</sup> Map of Mifepristone approval page. Gynuity website. Available at: [www.gynuity.org/documents/mife\\_approval\\_2007\\_map.pdf](http://www.gynuity.org/documents/mife_approval_2007_map.pdf). Accessed July 7, 2008.

<sup>9</sup> Map of Misoprostol Approval page. Gynuity website. Available at: [http://gynuity.org/downloads/map\\_miso\\_approval\\_aug08.pdf](http://gynuity.org/downloads/map_miso_approval_aug08.pdf). Accessed November 10, 2008.

<sup>10</sup> Mifepristone-Misoprostol page. WHO Essential Medicines Library website. Available at: [www.who.int/emlib/MedicineDisplay.aspx?Language=EN&MedIDName=443%40mifepristone%20+%20misoprostol](http://www.who.int/emlib/MedicineDisplay.aspx?Language=EN&MedIDName=443%40mifepristone%20+%20misoprostol). Accessed October 31, 2008.

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